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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
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EXAMINER
LILLING, HERBERT J

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 04/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/886,254	GUSYATINER ET AL.
	Examiner	Art Unit
	HERBERT J LILLING	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-23* is/are pending in the application.

4a) Of the above claim(s) *9 and 12-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7, 8, 10, 11 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *9 and 12-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4)☐ Interview Summary (PTO-413) Paper No(s). _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

1. Receipt is acknowledged of the amendment filed April 22, 2003.

2. Claims 1-23 are pending in this application.

3. This instant application is a RCE filed April 22, 2003. Claims 7,8, 10, 11 and 23 are drawn to the elected inventions. Claims 9, 12-22 have been withdrawn from consideration.

4. The prior rejections of Claims 7,8, 10, 11 and 23 have been maintained and is again recited as follows:

> **The Final Rejection has been maintained as stated. It is noted based on the current record, the instant specification has been considered by this Examiner to be fatally defective for the elected claimed inventions [Claims 7, 8, 10 and 11].**
>
> **The amendment to the claims will not be entered and considered in view of the fact that the amendment presents further consideration as well as does not materially reduce or simplify the issues. The additional information does not reduce the issues since the alleged improvement is not an absolute value but a comparison value that does not demonstrate that the value is a patentable distinction over the parent strain or any other mutated strain for the production of L-arginine in the presence of acetic acid or acetate as the only carbon source. The arguments have been deemed totally inadequate and factually incorrect with respect to the fact that the parent strain 237 noted in Table 2 does not produce arginine as well as that Table 3 is drawn to the presence of glucose and absolutely no acetic acid or acetate is present in the fermentation reaction. One of the basic issues which has not been addressed and supplied by Applicant is the requirement as noted by number (3) of page 5 of the remarks: "A description of the**

deposited biological material sufficient to specifically identify it and to permit examination;" which is commensurate in scope with the claimed inventions. The allegation that "Example 1 (page 8, line 4 to page 9, line 16), which fully describes characteristics of the deposited E. coli cell strains" has been considered to be totally inadequate for meeting the required material to specifically identify it and to permit examination. Applicant has failed to supply this information which sufficient factors includes A. > Morphological characteristics a. cells of the deposited strains as well as cells commensurate in scope with the claimed inventions incubated in various growth mediums and comparisons of the parent strains with the mutants with respect to (1) shape; (2) length/width; B. > Mode of proliferation; C.> Physiological characteristics (1) fermentation and (2) Assimilation comparisons of the parent strains versus the mutant strains.

Applicant has the opportunity to:

a. Submit more persuasive arguments;

b. Amendments;

c. Appeal Brief, which is reviewed by in-house 1600 Technical Center that is persuasive to require this Examiner to withdraw the rejection. If not, Examiner's Answer will be submitted to the Board of Appeals that may be reversed by the Board of Appeals.

d. Applicant would have the opportunity to submit either a RCE or a CIP to overcome the above rejections. It is very likely that only a CIP would be able to overcome the above rejections with respect to only deposited E. coli NTG strains 382 and 283 and mutants thereof.

The present claims 7, 8, 10, 11 and 23 stand rejected for the same above reasons. It is noted that this application stands rejected as based on a totally defective specification drawn to the elected inventions as not containing the information required. Applicant has submitted a decision to

support the allegations" "which fully describes characteristics of the deposited E. coli cell strains" [page 7 line 9] and the statement pertaining to the decision "Applicants note that the U.S. Courts have long held that availability of a biological product via a public depository provides an acceptable means of meeting the written description and enablement requirements of 35 U.S.C. 112 paragraph)see In re Argoudelis....). It is noted that this Examiner fully agrees with the above decision but the instant application does not meet the product requirements drawn to the deposited strain as well as the broad claimed microorganisms for which there are no deposits commensurate in scope with the claimed inventions. As for the microorganisms, there is a description requirement which the instant specification lacks that was met by the above decision, see page 4 which states "**A detailed taxonomic description of the microorganism was also disclosed.**"

As stated in the Final Rejection:

> In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification, See 37 CFR 1.803-37 CFR 1.809 for additional explanations of these requirements.

See the following paragraph pertaining to the lack of the identifying information:

> The language of the claims must make it clear what subject matter the claims encompass to adequately delineate their "metes and bounds". See, e.g., the following decisions: **In re Hammack**, 427 F 2d. 1378, 1382, 166 USPQ 204, 208 (CCPA 1970); **In re Venezia** 530 F 2d. 956, 958, 189 USPQ 149, 151 (CCPA 1976); **In re Goffe**, 526 F 2d. 1393, 1397, 188 USPQ 131, 135 (CCPA 1975); **In re Watson**, 517 F 2d. 465, 477, 186 USPQ 11, 20 (CCPA 1975); **In re Knowlton** 481 F 2d. 1357, 1366, 178 USPQ 486, 492 (CCPA 1973). The courts have also indicated that before claimed subject matter can properly be compared to the prior art, it is essential to know what the claims do in fact cover. See, e.g., the following decisions: **In re Steele**, 305 F 2d. 859, 134 USPQ 292 (CCPA 1962); **In re Moore** 439 F 2d. 1232, 169 USPQ 236 (CCPA 1969); **In re Merat**, 519 F 2d. 1390, 186 USPQ 471 (CCPA 1975).

"**The courts have also indicated that before claimed subject matter can properly be compared to the prior art, it is essential to know what the claims do in fact cover**."

The Claims fail to comply with the above decisions.

Thus, **it is impossible for an appropriate comparison between any claims drawn to a deposited claim or essentially for the broad claims as to the Patentability over any prior art.** The PTO does not possess the facilities to manufacture or to obtain and compare prior art microorganisms which is essentially the arguments presented absent the requirements that Applicant has refused to submit.

Applicant may have to go to the Board of Appeals to obtain any allowable claims absent the **taxonomic description of the microorganisms.**

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7, 8 and 10-11 **stand** rejected under 35 U.S.C. 102(b) as anticipated by Reference AW, McQuillen et al. for the same reasons as in the prior action **or under 35 U.S.C. 103 over the same reference.**

The disclosure of the reference teaches a microorganism that is considered to be within the scope of the claimed inventions absent a showing to the contrary, see the following:

It is well settled that if a reference reasonably teaches a product which is identical or substantially identical or are produce by identical or substantially identical process, the PTO can require an applicant to prove that the prior art products do not inherently possess the characteristics of his claimed product. A rationale given for shifting the burden of going forward to applicant is that the PTO does not possess the facilities to manufacture or to obtain and compare prior art products, see **In re Brown**, 459 F.2d 531, 535,173 USPQ 685, 688 (CCPA 1972); **In re Best**, 562 F.2d 1252, 1255,195 USPQ 430, 433-434 (CCPA 1977).

Claims 7 and 10 clearly anticipates the claimed inventions. The burden is on Applicant to show that the reference microorganism does not absolutely produce arginine in a medium containing acetic acid or acetate as the lone source. The instant specification only indicates that the strain on page 8 grows poorly but there is absolutely no indication that no arginine was produced. In any event, the burden is on Applicant to show that the reference product is not within the scope of the claimed inventions especially in view of the incomplete compliance with the Rules of Deposit.

The arguments are drawn to "In contrast, a mutant strain, which was modified..." which limitations are not present in the instant claims. The data in Tables 2 and 3 are drawn to "mutant" strains, for which this limitation is not described in the instant claims.

The claims are drawn to a broad generalized E.coli strains which have been isolated having an ability to do something but does not indicate the intrinsic properties of the strains.

The cited reference discloses a strain which appears to be identical to the presently claimed strain, since it has properties that are within the scope of the claimed invention as demonstrated by the Tables. The enhancement does not indicate what is required for the enhancement which modification can be any process whereby arginine is increased.
OR

The referenced microorganism appears to be identical to the presently claimed strain and is considered to anticipate the claimed microorganism since the strain produces the same products. Consequently, the claimed strain appears to be anticipated by the reference.

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed strain would have been obvious to those of ordinary skill in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain **a written description of the invention**, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7,8 and 10-11 are rejected under 35 U.S.C. § 112, first paragraph, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention with respect to the claimed language which is considered to be extremely broad for the microorganism

The specification lacks adequate written description for the claimed inventions in view of the following points in accordance with the written description requirements of 35 U.S.C. 112:

The description must clearly allow persons of ordinary skill in the art to recognize what is claimed. Thus, an applicant must comply with the written description requirement "by describing the invention, with all its claimed limitations, not that which

makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966. An **adequate written description** of the microorganisms requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

The **description requirement** of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

The broad generic claim lacks sufficient description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing since the specification lacks a sufficient number of microorganisms which have been described by complete structure or identifying characteristics, thus the description requirement has not been satisfied.

7. **No claim is allowed.**

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Examiner Lilling whose telephone number is (703) 308-2034** and **Fax Number** is for applications **Before Final** (703) 872-9306 and **After Final** for applications is 703-872-9307 or SPE Michael Wityshyn whose telephone number is (703) 308-4743. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

H.J.Lilling: HJL
(703) 308-2034
Art Unit **1651**
April 29, 2003

Dr. Herbert J. Lilling
Primary Examiner
Group 1600 Art Unit 1651